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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Appln. Of:	SMITS et al.		
Serial No.:	09/600,732		
Filed:	July 20, 2000		
For:	PROCESS FOR THE MANUFACTURE OF CHICORY...		
Group:	1637	Confirmation No. 8993	
Examiner:	Chunduru, Suryaprabha	DOCKET:	TIENSE RAFF.26

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPELLANTS' SUBSTITUTE REPLY BRIEF

In connection with the above entitled matter, enclosed please find Appellants' Substitute Reply Brief in response to the Examiner's Substitute Answer mailed November 14, 2006.

The Board is respectfully requested to substitute the attached Substitute Reply Brief for the Reply Brief previously filed.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account No. 08-1391.

Respectfully submitted,

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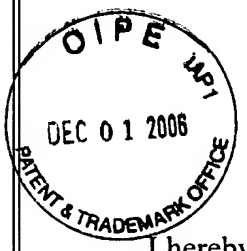

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APPELLANTS' SUBSTITUTE REPLY BRIEF UNDER 37 CFR 1.193 (b)

This Substitute Reply Brief is being filed in response to the new points of argument raised in the Examiner's Substitute Answer mailed November 14, 2006. Appellants respond to these new points of argument as follows:

I. The rejection of the claims under 35 USC §103 as obvious from the art is in error.

The Examiner has reopened prosecution ostensibly based on new weather data for Ukkel/Brussels from "The Royal Institute of Meteorologique Center, Belgium". In his Substitute Answer, the Examiner characterizes the earlier BPAI reversal decision (earlier Appeal No. 2004-1498) as follows:

> "The decision indicated that the examiner offers no evidence to support for optimization conditions of the conventional chicory inulin growing process and no evidentiary support to show that the prior art, Van den Ende et al., performed the study during the time period at which the temperatures never dropped below minus 1° C in Heverlee, Belgium...To address the issue of the temperature, the Examiner reopened the prosecution and provided meteorological data from The Royal Institute of Meteorological Center, Belgium for the

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> year 1994, during which time Van Den Ende et al. performed their study. The current grounds of rejection includes the new reference (meteroplogical data from the Royal Institute of Metereological Center, Belgium for the year 1994) which was not present at the time the decision was made in the appeal No. 2004-1498."

This data, despite the Examiner's assertions to the contrary, is no different from that considered in the earlier BPAI reversal decision (earlier Appeal No. 2004-1498) where the Board stated that such data was speculative for the rural village of Heverlee and insufficient to overcome the Examiner's burden of establishing a prima facie case for obviousness. (See BPAI Decision in Appeal No. 2004-1498 at page 12). The Examiner states that "Appellants' assertions are not proper because the Examiner provided the temperature data from RMI after the earlier BPAI decision" (Examiner's Answer at page 13). This statement is not quite true: the previous appeal considered data of "Belgium's weather from a website." This website data is the same as the RMI data. This meteorological data has confusingly been referred to under different names throughout the prosecution of this application, such as being the data for "Ukkel" and being the data for "Brussels," and originating from "The Institute Royal Meteorologique de Belgique," "The Royal Institute of Meteorologique Center, Belgium," "Royal Institute Report," "RMI,"" and "Belgium's weather from a website." Even under such a multitude of monikers, the collected data are the same, were collected from the same site, and were collected by the same institution. The Examiner, however, obstinately fails to recognize the Board's prior rejection of this data and instead attempts to shift the burden of proof to the Appellants by requiring the Appellants to furnish historical temperature data from the town of Heverlee. As previously stated in the record, Appellants do not possess this data. Moreover, there is no meteorological center maintained in Heverlee, and the fact the inventors of the subject application thought to monitor temperatures for their study does not mean that any one of them would have thought to

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monitor the temperature in previous studies.[1] (See Examiner's Answer at pages 13-14). Simply, the Appellants cannot furnish what they do not possess.

Notwithstanding the foregoing, in an attempt to assuage the Examiner, Appellants provided historical temperature data that were available from the nearby rural town of Herent. Appellants note that while this data is obtained from a point closer in geography, as well as in other temperature affecting variables, such as size and population, the data is nonetheless no better than the temperatures offered from Ukkel/Brussels to prove the temperature in Heverlee. What this data does establish, however, is that neither sets of temperature can be juxtaposed on to Heverlee as the two data sets differ. Appellants also point out that the temperatures in Herent did drop below zero on two days during the essential growth period. The Examiner asserts that the "new data on temperature for Herent on October 18 is relatively closer to the temperature data provided by the Examiner for Ukkel on that day." (Examiner's Answer at pages 15-16). This statement simply makes no sense as, apart from the fact that there is no other point for the Herent temperature to be relatively closer to Ukkel from, the temperature in Herent did reach – 1.1°C on October 18. As a result, chicory grown in Herent would have the FEH gene triggered on that day.

The Examiner rejects Appellants' data from Herent which in fact is much closer (about 3-4 times closer) to Heverlee than Ukkel (the KMI data provided by the Examiner relate to Ukkel). Appellants set forth that if the Examiner's argument stipulating that the KMI data from Herent submitted by Appellants do not provide proof of the temperature situation in the adjacent

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[1] The fact that the same parties did not collect the temperature data during the Van den Ende et al. study also lends itself to rebut an obviousness rejection: namely that it was not obvious during the study that unconventional climatological conditions are necessary to avoid triggering the FEH gene and thereby impede fructan degradation.

location Heverlee, would be accepted by the Board, the Examiner's argument should *a fortiori* also have to apply to the KMI data from Ukkel submitted by the Examiner, because Ukkel is about 3-4 times further removed from Heverlee than is Herent from Heverlee.

Appellants submit that the Board of Appeal has already decided patentability of the instant claimed invention in the earlier BPAI reversal decision, which thus has become "res judicata", and that said decision was taken with consideration of the KMI data for Ukkell submitted by the Examiner. Consequently there are in fact no new elements in the case apart from the KMI data provided by Appellants regarding the temperature conditions in Herent, which is about 3-4 times closer to Heverlee where the VDE study was made than the KMI data from Ukkel previously provided by the Examiner, and apart from the fact that Appellants' KMI data from Herent support Appellants' statement that during the 189 days of the VDE experiment, the temperature in Herent, and hence most probably also in Heverlee, has dropped below minus 1°C, in contrary to the Examiner's allegation.

Finally, Appellants emphasize that, contrary to the conventional cultivation of chicory roots which are seeded and grown when there is no longer danger for the occurrence of frost, low temperature conditions (below minus 1°C) may occur during a well defined period of the growing period according to the subject invention as indicated in claim 65, the sole independent claim on appeal (from the beginning of the third month of the growing period...), without adverse effects on the inulin production in the chicory roots or on the chain length (degree of polymerisation) of said inulin. This feature is nowhere disclosed, nor taught, nor suggested in the cited prior art or in a combination of the said three prior art documents.

The Examiner raises four questions in his Answer:

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> "First, does Applicant have separate temperature information for Heverlee, Belgium, for the period of June 1, 1994 to December 9, 1994. Second, does Applicant have evidence regarding triggering of the fructan exohydrolase gene by low temperature during the growth period of chicory. That is, was the temperature low enough to trigger this gene or not? Third, did the temperature during chicory's growth conditions ever drop below –1 degree Celsius? Fourth, is Applicant aware of the longest period of cultivation of the chicory by Van den Ende? It appears to be 189 days, is this correct?" (Examiner's Answer at page 12).

Appellants' respond as follows:

In answer to the first question, as noted supra, Appellants do not have the temperature data for Heverlee in 1994. The second and third questions are vague as to whether they inquire into the Van den Ende et al. study or the present application. With regard to the Van den Ende et al. study, it seems from the data that the FEH gene was triggered after October 15, but the temperatures remain unknown. (See Van den Ende et al. at Figure 4, page 47). With regard to the present application, these questions are answered by the Specification and the claims which explicitly teaches the role of FEH and how it is triggered. With regard to the fourth question as has been mentioned previously and noted by the Board in the earlier BPAI decision, the length of cultivation by Van den Ende et al. is not the major factor, but the temperatures the chicory is exposed to is. The present claimed invention demands a growth period of over 180 days, AND that the chicory not be exposed to temperatures below -1°C during such a growth period.

With regard to the Examiner's continued statements regarding the observations of Van den Ende et al. (Plant Physiol. Vol. 149: 43-50, 1996), Van den Ende et al. does not relate to a method for an improved process for the cultivation of chicory roots, and in particular not to the cultivation of chicory roots outside the conventional cultivation and harvesting season. Rather, Van den Ende et al. is primarily a study of the inulin synthesizing enzymes (FFT (fructan

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fructosyl transferase) and SST (sucrose fructosyl transferase)) in chicory roots during growth, storage and forcing of the roots. Van den Ende et al. also provides potential explanations for the degradation of fructans cultivated under conventional growth conditions, and this, not in view of the production of inulin and oligofructose, but in view of the production of shoots of chicory, i.e. the vegetable Belgian Witloof (also known as Belgian andive). The Examiner repeatedly points to the observation by Van den Ende et al. that growth, storage and forcing affect the FFT activity and that "cold storage" increases the depolymerization of large fructans and with a simultaneous increase in smaller fructans. The Examiner then leaps from observations focusing on the activity of FFT in cold storage at +1°C to conclude that a temperature of -1°C triggers FEH gene activity. The Examiner's assertion about the 189 days growing period without the occurrence of a temperature of minus 1°C (Examiner's Answer, p. 5) is vigorously contested because it is based on the Examiner's erroneous view that the FEH gene has not been triggered during the period of VDE's experiment (from June 1st to December 6th), and that low temperature conditions of minus 1°C only occurred after said period, namely on December 15 and 16, 1994.

As has been previously pointed out, Van den Ende et al. teaches that the cold storage is at a temperature of +1°C, illustrating there is no teaching or suggestion made of achieving/avoiding the requisite -1°C, nor that exposure to such a lower temperature triggers the FEH gene. (See Van den Ende at page 44, left column first full paragraph). Van den Ende et al. notes fluctuations in FEH gene activity during their study (See Van den Ende et al. at Fig. 4, pg 47), but is silent with regard to how FEH activity may have been affected. In fact, in the conclusion of the Van den Ende et al. reference, it is speculated that the disappearance of the other fructan synthesizing enzyme, SST, may allow the FFT to act in fructan catabolism and, therefore, that it

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is actually the FFT enzyme that is responsible for the changes seen. (See Van den Ende et al. at page 49, left column). Van den Ende et al. therefore would lead one skilled in the art to believe that it is the FFT acting without the SST that causes the fructan degradation. Van den Ende et al. is silent with regard to both the temperature reaching -1°C and that such a temperature triggers the activity of the FEH gene. Therefore, no reading of Van den Ende et al. could possibly supply a skilled artisan with the knowledge that avoiding -1°C is necessary to avoid triggering the FEH enzyme. Furthermore, no reading of Van den Ende et al. would teach or suggest to a skilled artisan that utilizing unconventional climatological conditions would result in inulin with a higher degree of polymerization.

With regard to the Examiner's use of the Yamazaki et al. (U.S. Patent No. 4,613,377) reference, this too fails to supply the missing teachings with regard to the necessary climatological conditions. Simply, Yamazki et al. teach a process for the preparation of fructo-olyosaccharides and fructose by partial or substantially complete hydrolysis of inulin from an aqueous solution containing inulin from Jerusalem artichoke or from chicory roots, and are completely silent on even a suggestion of a way to produce inulin with a higher average DP (degree of polymerization). Yamazaki et al. does not address the provision of the source material for inulin extraction, but at best recites some non-specific information regarding the conventional cultivation of Jerusalem artichoke (See Yamazaki et al,. Abstract and Col. 10, lines 36-40; Col. 10, line 58 to Col.11, line 4, and US '377, Col. 10, lines 58-68; Col. 12, lines 24-27) and that chicory can be used as a less preferred alternative source (See Yamazaki et al. at Col. 12, lines 24-27). In other words, Yamazaki et al. neither discloses nor suggests a method for improvement of processing (obtaining) of chicory inulin from chicory roots, but merely discloses

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a method for the manufacture of fructo-oligosaccharides and fructose from an aqueous solution of inulin. The disclosure of Yamazaki et al. about inulin is merely generic in the way that the Yamazaki et al. process starts from the tubers or roots to provide via extraction the conventional source material (aqueous inulin solution) for the Yamazaki et al. process (Yamazaki et al., Col. 12, lines 45-51).

As to the cultivation of the plant source of the inulin, Yamazaki et al. just briefly and in a very generic manner mentions that inulin can be obtained from tubers of Jerusalem artichoke and from chicory roots, but is absolutely silent about the essential feature of the subject invention which boils down to an improved method for providing said roots of chicory by seeding, growing, harvesting, storing and processing the chicory roots under very particular conditions.

Yamazaki et al.'s specific disclosure "that the source material for the process "can be grown well in colder conditions, even in waste land" and "Jerusalem artichoke tubers can be efficiently produced and harvested in late October and ideally should be processed within a few months" Yamazaki et al., (Col. 12, lines 3-9 and lines 21-24) clearly relates only to tubers of Jerusalem artichoke, is silent about storage conditions, and does not give clear teaching that said feature also applies to chicory roots source material. Assuming *arguendo,* even if Yamazaki et al. would be considered to include such teaching, then said teaching would still not be relevant because "colder conditions" is undefined and gives no information at all about the specific conditions, namely the low temperature requirements that may trigger the FEH gene as well as about the particular part of the growing period during which temperature conditions of lower than minus 1°C are even allowed under the subject patent application. The feature "even in waste land" appears not relevant at all regarding the subject patent application.

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The Yamazaki et al. disclosure that "...the inulin may also be derived, in a similar fashion, from the roots of chicory or dahlia" (Col. 12, lines 26-27) is clearly merely generic and is absolutely silent about the particular features for seeding, growing, harvesting and processing chicory roots according to the subjection invention. In other words, Yamazaki et al. fails to teach unconventional cultivation/provision methods to avoid triggering the FEH gene in order to achieve inulin with a higher average DP. Therefore, no reading of Yamazaki et al. would supply the missing teachings to render the present application obvious.

With regard to the Examiner's use of the Van Loo et al. (U.S. Patent No. 5,660,872) reference, this relates to a method for processing inulin, whereby an aqueous solution of a polydisperse saccharide composition comprising mono-, di-, oligo-, and polysaccharides, is fed in a metastable state into a chromatography column, and then eluted with warm water and separated into various fractions, thus providing a fraction of inulin that is free from saccharides of a degree of polymerisation of less than or equal to 2. That is to say, Van Loo et al.'s disclosures only relate to the manufacture of a particular grade of inulin, namely inulin from which monomeric and dimeric saccharides (glucose, fructose and sucrose) have been removed via a chromatographic separation step in which an aqueous solution of inulin, conventionally obtained from chicory roots that in turn have been obtained from conventionally cultivated chicory roots, has been subjected. Van Loo et al. is clearly not related to the essential aspect of the subject claimed invention, namely cultivating chicory roots as source material for the manufacture of inulin or inulin hydrolysates under seeding, growing, harvesting, storing and processing conditions that partly or completely fall outside conventional cultivation and harvesting conditions. Therefore, Van Loo et al. also fails to add any teaching to render the

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present invention obvious.

In sum, none of the references relied on by the Examiner can be combined to render the present invention obvious. No reference teaches the essential aspect of utilizing unconventional climatological conditions to avoid triggering the FEH gene and thereby produce inulin with a higher degree of polymerization.

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CONCLUSION

None of the cited documents, namely Yamazaki et al., Van Den Ende et al. and Van Loo et al., disclose or suggest the claimed subject matter of the present patent application. They are clearly not relevant to the subject invention and do not provide to the skilled person any teaching that points to the subject invention. Besides, none of the prior art documents contains any teaching, suggestion or any incentive for the skilled person to combine the references. Even if the skilled person would combine the teaching of these three references, there still would be no teaching pointing to the subjection invention which would in fact still remain non-obvious in view of said combined teachings.

In view of the foregoing, it is respectfully submitted that the Examiner's Final Rejection of the subject Application is in error, and it is requested that the Rejection be reversed in all respects.

Respectfully submitted,

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